K122694

510(k) Summary

OCT 25 2012

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	August 15, 2012
Submitter:	GE Hangwei Medical Systems Co.,Ltd. No.2, Yong Chang North Road Econ. & Tech. Development Zone Beijing, 100176, P.R.China
Primary Contact Person:	Ms. Zhirong Huang Regulatory Affairs Leader GE Hangwei Medical Systems Co., Ltd. Phone: +86 10 58068888 70236 Fax: +86 10 67803267 Email: Zhirong.Huang@ge.com
Secondary Contact Person:	Mr. Glen Sabin Regulatory Affairs Director GE Healthcare (GE Medical Systems, LLC) 3200N Grandview Blvd., Mail Coil-W-827 Waukesha, WI 53188, USA Phone: +1 262 521 6848 Fax: +1 262 521 6439 Email: Glen.sabin@ge.com
Device: Trade Name:	GE 8CH Foot Ankle Coil
Common/Usual Name:	Coil, magnetic resonance, specialty
Classification Names:	21CFR 892.1000, Magnetic resonance diagnostic device
Product Code:	90MOS
Predicate Device(s):	K050514, Foot Ankle coil （MRI Devices Corporation, which known as Invivo Corporation）
Device Description:	The GE 8CH Foot Ankle Coil is a surface coil used for Magnetic Resonance Imaging. It's tuned to image Proton

nuclei in a receive-only configuration. It is comprised of 8 individual Phased Array coil elements each utilizing an integrated preamplifier to improve image quality. The geometry is optimized for use with parallel imaging techniques.

The GE 8CH Foot Ankle Coil comprises the coil and the base plate. The coil conforms to patients' anatomy, accommodating various foot contours while minimizing patient discomfort. The base plate separated from the coil part is used to place the patients' anatomy on the table.

Intended Use:

The GE 8CH Foot Ankle Coil is a receive-only RF surface coil designed for use with 1.5T MRI systems manufactured by GE Healthcare. The 8ch Foot Ankle Coil for GE 1.5T MRI systems is indicated for use for foot and ankle imaging. The nucleus excited is hydrogen.

Technology:

The GE 8CH Foot Ankle Coil is 8-element phased array RF receive only coils with integrated preamplifiers. The coil designs consist of RF chokes with switching diodes to provide decoupling which isolates the coil elements from RF fields during RF transmission. This coil is designed based on the same technology as the predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

Verification testing has been performed and is documented in the sections noted below of this submission. The following verification tests have been performed:

1. Biocompatibility Testing (section 15)
2. IEC 60601-1-2 testing (section 17)
3. IEC 60601-1 testing and NRTL certification to UL 60601-1 (section 17)
4. IEC60601-2-33 testing (section17)
5. Maximum B1 Peak test – This test is to verify the coil's ability to withstand maximum B1 peak fields and high B1 field energy concentrations without posing a risk to safety through arcing or voltage breakdown. (section 18)
6. Signal to Noise ratio and uniformity test according to

NEMA standard (section 18)

7. Blocking Network analysis - This test determines the effectiveness of the blocking networks(s) for transmit decoupling to ensure safety and to minimize B1 distortion. (section 18)
8. Surface temperature test – normal condition (section 18)
9. Surface temperature test – unplugged condition (section 18)

Summary of Clinical Tests:

Sample clinical images included in Section20 Performance Testing-clinical were performed within GE Healthcare facilities under the control of GE Global Research Study Work Instruction.

Conclusion:

GE Healthcare considers the GE 8CH Foot Ankle Coil for 1.5T MRI systems to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT 25 2012

GE HANGWEI Medical Systems Co., Ltd.
% Mr. Glen Sabin
Regulatory Affairs Director
GE Medical Systems, LLC
3200 N. Grandview Blvd. Mail Code-W-827
WAUKESHA WI 53188

Re: K122694
Trade/Device Name: GE 8CH Foot Ankle Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: August 15, 2012
Received: September 6, 2012

Dear Mr. Sabin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122694

Device Name: GE 8CH Foot Ankle Coil

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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